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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/780,917

02/19/2004

Lesley Murray

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11/16/2006

PFIZER INC

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SAN DIEGO, CA 92121

EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/780,917

Applicant(s)

MURRAY ET AL.

Examiner

Shirley V. Gembeh

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9, 11 and 12 is/are allowed.
- 6) ☒ Claim(s) 1-8 and 13- 14 is/are rejected.
- 7) ☒ Claim(s) 10 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/17/05; 5/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's election with traverse of Group I, claims 1-5 and 13-15 in the reply filed on August 14, 2006 is acknowledged. Applicants' argument is found persuasive as addressed. Applicant notes that the compound of formula I r is 0 as in compound of formula II the restriction requirement is therefore vacated and withdrawn. Thus claim 6 has been interpreted not to differ from compound of formula I.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 3/17/05 and 5/19/04 have been received and acknowledged.

Claim Objections

Claims 10 and 15 are objected to because of the following informalities: The abbreviation M-CSF and CSF1R should be given as its full name or with the full name in parenthesis therewith when first used. Appropriate correction is required.

Allowable Subject Matter

Claims 9, 11-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1- 8, 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating cancer that has metastasized to the bones, osteoporosis and post menopausal patients does not reasonably provide enablement for treating excessive osteolysis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2nd 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

Nature of the Invention: The claims are drawn to a method of treating excessive osteolysis in a patient administering a compound of formula I.

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The nature of the invention is extremely complex in that the skilled artisan would not be able to determine what is defined by excessive osteolysis, at what point do you consider the disease is excessive osteolytic.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass treating a wide representation of excessive osteolytic disease without defining what these osteolytic disease entails with the claimed compound of formula I.

Guidance of the Specification: The guidance given by the specification as to how one would determine the disease to be excessive osteolytic is absent.

Working Examples: All of the working examples provided by the specification are directed toward the synthesis of the various compounds and the treatment of inhibition of phosphorylation of colony stimulating factor 1 receptor (CSF1R), inhibition of murine osteoclast, breast cancer and breast cancer metastasis.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual treatment of excessive osteolysis in a patient with the claimed compounds makes practicing the claimed invention unpredictable in terms of identifying what disease would be class under the term excessive osteolysis.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first have to determine when does the disease becomes excessive osteolysis, compound dosage, duration of treatment, route of administration, etc. the appropriate animal model determine whether or not the compound is effective for the particular osteolytic condition in the said population type.

Level of ordinary skill in the art.

The level of ordinary skill in the art is high. Hence, the specification fails to provide sufficient support of the broad use of the compounds of the claims for the treatment of excessive osteolysis with the claimed compound. As a result necessitating one of skill in the art to perform an exhaustive search to determine which diseases can be termed excessive osteolysis treated by what compounds of the instant claims in order to practice the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 11/13/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER